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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,217	09/15/2003	Tianmei Ouyang	LIFE-070DIV	2349
24353	7590	03/26/2004	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP			DO, PENSEE T	
200 MIDDLEFIELD RD			ART UNIT	
SUITE 200			PAPER NUMBER	
MENLO PARK, CA 94025			1641	

DATE MAILED: 03/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/663,217	Applicant(s) OUYANG ET AL.	
	Examiner Pensee T. Do	Art Unit 1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Specification***

In the cross-reference section, please update the status of the parent application 09/513,217 (which is now patent 6,656,697).

### ***Amendment Entry & Claim Status***

The preliminary amendment filed on September 15, 2003 has been acknowledged and entered.

Claims 1-5 are pending. Claims 6-22 are cancelled.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 6, 11, 12, of U.S. Patent No. 6, 656, 697 in view of Freitag (EP 0654079B1).

Patent '697 teaches a dry reagent strip for determining the presence and amount of analyte in a hemoglobin-containing biological fluid comprising a support layer on which is a test pad and a reagent comprising:

- a flavin-dependent enzyme that has flavin bound to it and that has specificity for the analyte;
- nicotinamide adenine dicleotide (NAD) or an NAD derivative;
- a tetrazolium dye precursor;
- phenazine methosulfate (PMS) or an analog thereof; (equivalent to the electron transfer agent) and
- a nitrite salt.

The enzyme is glucose oxidase and the analyte is glucose.

However, Patent '697 fails to disclose water-soluble dye-precursor and divalent metal stabilizer.

Freitag teaches a reagent comprising an enzyme, a phenazine derivative, a tetrazolium salt; and a divalent metal salt to stabilize the phenazine/tetrazolium salt system (page 2, line 50-page 3, line 19).

Since patent '697 teaches the use of a reagent containing the combination of phenazine and tetrazolium salt, it would have been obvious to one of ordinary skills in the art to incorporate the divalent metal salt taught by Freitag in the reagent of patent '697 because Phenazine/tetrazolium salt reagent system become unstable at pHs above 5.5. Therefore, the divalent metal salt is used to stabilize the

phenazine/tetrazolium salt system at pHs from about 5.5 to about 7.8, thereby permitting the optimal functioning of certain enzymes (page 2, line 50-page 3, line 19).

Regarding claim 3, since patent '697 teaches that the reagent containing the dye precursor is used for measuring a concentration of analyte in a hemoglobin-containing biological fluid, it is inherently that the dye precursor must be water-soluble in order to be used in a biological fluid sample.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/663,217  
Art Unit: 1641

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Pensee T. Do  
Patent Examiner  
March 17, 2004

  
CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP ~~1800~~ 1641